



# PROJECT MANAGEMENT PLAN GALAXY

## GUT-AND-LIVER AXIS IN ALCOHOLIC LIVER FIBROSIS GRANT NUMBER 668031

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## **1. INTRODUCTION**

The EU Framework Programme for Research and Innovation Horizon 2020 has granted the GALAXY project 6.3 million  $\notin$  to investigate the gut-and-liver axis in alcoholic liver fibrosis under the grant number 668031.

GALAXY was initiated on January 1<sup>st</sup> 2016, and will continue until January 1<sup>st</sup> 2022.

The purpose of this management plan is to outline the overall infrastructure of the management approach for the project. It serves as a central guide in regards to daily managing of the overall project progression, reporting, meeting schedules, templates and communication between GALAXY members.

## **2.** LEGAL BASIS

The GALAXY project operates within the Horizon 2020 Framework Programme.

Responsibilities towards the funding party, the European Commission, are stated in the Grant Agreement Nr 668031.

The roles and responsibilities of the parties towards each other are stated in the Consortium Agreement that has been signed by all partners.

The GALAXY Consortium Agreement (CA) and Grant Agreement (GA) are at all times superior to this management plan.

## **3. PROJECT OBJECTIVES**

The objective of the GALAXY project is to effectively employ integrated system modeling of multi-omics data together with clinical data, to develop prevention and treatment programs for alcoholic liver fibrosis (ALF). By use of systems biology approach the project investigates the role of the gut microbiome in alcoholic liver fibrosis.

The specific aims are:

- 1. To define specific gut microbiome and associated host genome, transcriptome and metabolome key networks and risk signatures that predict the development and progression of ALF.
- 2. From these signatures to develop novel 'omics-based biomarkers tailored for early diagnosis, prognosis and treatment monitoring. The goal is to enable timely interventions and prevent advanced disease.
- 3. Verify discovered key networks in animal models and validate biomarkers in an interventional clinical study.
- 4. Evaluate interventions based on microbiome modulation to prevent ALF progression



## **4. PROJECT STRUCTURE**

#### **4.1 CONSORTIUM PARTNERS**

The GALAXY consortium consists of 10 partners in 4 countries.

| #  | Partner Name                                      | COUNTRY |
|----|---|---------|
| 1  | University of Southern Denmark (coordinator)      | Denmark |
| 2  | Odense University Hospital                        | Denmark |
| 3  | European Molecular Biology Laboratory             | Germany |
| 4  | University of Copenhagen                          | Denmark |
| 5  | Biomedical Research Foundation, Academy of Athens | Greece  |
| 6  | Universitetsklinikum Bonn                         | Germany |
| 7  | Steno Diabetes Center A/S                         | Denmark |
| 8  | Nordic Bioscience A/S                             | Denmark |
| 9  | University of Oslo                                | Norway  |
| 10 | Nordic Rebalance A/S                              | Denmark |

## **4.2 ORGANIZATIONAL STRUCTURE OF GALAXY**

The organizational structure of GALAXY is shown in the diagram below.



#### 4.2.1 EUROPEAN COMMISSION

The European Commission is the grant giver. All responsibilities towards the grant giver are stated in the Grant Agreement.



#### 4.2.2 The Steering Committee

The Steering Committee is GALAXY's central managerial body and responsible for decisionmaking within the GALAXY consortium. Project Coordinator Aleksander Krag chairs the Steering Committee. The committee is responsible for any decisions regarding alterations in the forwarded strategy of the project, budget alterations or changes in allocations of resources available.

Voting rules are described in detail in the Consortium Agreement. Each member has one vote.

During meetings any partner can participate with additional representative from their institutions, as long as voting rules are respected.

The composition of the Steering Committee is designed to cover all the essential activities in GALAXY, consisting of all work package leaders and special managers. All partners are represented in the Steering Committee and the partner representative in the Steering Committee is authorised, on behalf on their institution, to make decisions on all matters of discussion in the Steering Committee. All partners can submit resolutions for consideration by the Steering Committee.

| ΝΑΜΕ              | INSTITUTION                                       |
|-------------------|---|
| Prof Krag         | University of Southern Denmark                    |
| Dr Madsen         | Odense University Hospital                        |
| Dr Arumugam       | University of Copenhagen                          |
| Prof Hansen       | University of Copenhagen                          |
| Prof Oresic       | Steno Diabetes Center A/S                         |
| Prof Trebicka     | Universitetsklinikum Bonn                         |
| Prof Melberg      | University of Oslo                                |
| Prof Bork         | European Molecular Biology Laboratory             |
| Prof Anastasiadou | Biomedical Research Foundation, Academy of Athens |
| Dr Thiele         | Odense University Hospital                        |
| Prof Karsdal      | Nordic Bioscience A/S                             |
| Dr Israelsen      | Nordic Rebalance A/S                              |

Following representatives constitutes the Steering Committee:

The Steering Committee is directly advised from the Advisory Board. The dissemination manager (prof Trebicka) together with the project coordinator (prof Krag) will be responsible for the overall contact with the advisory board. Plans for meeting activities of the Steering Committee is outlines in section 7.1.3.

#### 4.2.3 The Coordinator

The Coordinator is the link between the grant giver – the Commission – and the grant takers – the GALAXY consortium. The Coordinator oversees project progression, and the roles are clarified in section 4.3.1.



#### 4.2.4 WORK PACKAGE LEADERS

GALAXY is divided into 8 specific work packages (WP). A person in charge has been appointed for each work package.

| WP# | WP TITLE   | LEAD<br>BENEFICIARY | WP LEADER   | Start<br>Month | End<br>Month |
|-----|--|---------------------|-------------|----------------|--------------|
| WP1 | Clinical studies                                       | OUH                 | M. Thiele   | 1              | 72           |
| WP2 | Multi-omics studies of<br>host and gut microbiome      | EMBL                | P. Bork     | 1              | 57           |
| WP3 | Metabolomics and biochemical assays                    | Steno A/S           | M. Oresic   | 1              | 57           |
| WP4 | Bioinformatics and<br>systems modeling                 | EMBL                | P. Bork     | 6              | 60           |
| WP5 | Animal studies and<br>hepatic fibrogenesis             | UKB                 | J. Trebicka | 1              | 48           |
| WP6 | Biomarker development:<br>evaluation and validation    | NB                  | M. Karsdal  | 28             | 66           |
| WP7 | Socio-economic<br>evaluations                          | UO                  | H. Melberg  | 36             | 72           |
| WP8 | Project management,<br>dissemination,<br>communication | USD                 | A. Krag     | 1              | 72           |

The WP leader is responsible for overseeing the progress of their respective work package and ensures the scientific quality of the work performed. They furthermore hold responsibility for the preparation of both internal progress reports with in the scope of the project, and provide reports for the project management office in order to carry out the financial and periodic reports to the European Commission. The WP leader is responsible for notifying both the project management office and the Steering Committee in case of delays in fulfillment of deliverables and milestones. The WP leader holds responsibility for identifying and managing the risks within their work packages.

#### 4.2.5 Advisory Board

GALAXY has installed an external advisory board with the main purpose to provide GALAXY with a continuous 'fresh' and independent input on its activities and results. This external advisory board does not have decision authority in the project, but will provide the GALAXY Steering Committee with ex-ante advice and ex-post feedback on the activities and results of GALAXY, from their respective backgrounds, interests and expertise. They will have full confidential access to all the GALAXY documentation they need in order to form their expert opinions and will be invited to selected project meetings. The Advisory Board will consist of key opinion leaders in the field of gut-liver axis and research in alcoholic liver fibrosis. Additional



members may come during the projects life span. The current Advisory board consists of:

| ΝΑΜΕ             | INSTITUTION                 |
|------------------|-----------------------------|
| Prof Szabo       | University of Massachusetts |
| Prof Schnabl     | University of California    |
| Prof Shah        | Mayo Clinic                 |
| Prof Lotersztjan | University of Paris         |
| Prof Wiest       | Bern University Hospital    |

#### 4.2.6 Special Managers

Special managers have been appointed to set attention to areas of special interest in order to maximize impact of work. The managers are overall responsible for progression of their special area (e.g. dissemination). Compilation of management plans describing the action for the particular area (e.g. exploitation plan) are supported by the project management office, where the project manager will assist in writing up the plan, and the appointed manager takes active part in the strategy of this plan. All partners are expected to participate in maximizing input of the work, and both information on e.g. risks and dissemination activities will be a standard topic in the internal progress reporting.

The appointed managers and their primary tasks are:

| MANAGEMENT AREA NAME                   |                  | PRIMARY TASK   |  |  |
|--|------------------|--|--|--|
| <b>Dissemination</b> J. Trebicka (UKB) |                  | Results broadcasted to stakeholders identified<br>as health care providers, industry, policy<br>makers, patients, scientific community |  |  |
| Risk                                   | T. Hansen (UCPH) | Assisting WP leaders in identification and resolution of critical risks, conflict resolution.  |  |  |
| Innovation                             | P. Bork (EMBL)   | Supporting WP leaders in innovative tasks  |  |  |
| Exploitation                           | M. Karsdal (NB)  | Development of exploitation strategy   |  |  |
| Ethics                                 | B. Madsen (OUH)  | Overseeing ethical standards   |  |  |

#### **4.3 MANAGEMENT STRUCTURE IN GALAXY**

The Project Coordinator, Aleksander Krag, and Project Manager, Linda Sevelsted Møller, has the overall authority and responsibility for managing and executing all management related issues of the project according to this Management Plan. They constitute the Project Management Office, as part of work package 8. The Project Management Office has assistance from legal and financial personal at the University of Southern Denmark, and is further supported from appointed special task managers, as elaborated in section 4.2.6.

The main task of the Project Management Office includes development of internal technical and financial progress monitoring, reporting, planning of meetings and delivery of financial-administrative and managerial support in order to disseminate.



The Project Management Office will be a matrix in that the *appointed leaders from each work package must continue to report to their project progression throughout the duration of the project.* The project manager is responsible for communicating with work package leaders on the progress and performance of each project resource.

#### 4.3.1 Project Coordinator

Professor Aleksander Krag Department of Gastroenterology and Hepatology University of Southern Denmark Sdr. Boulevard 29 5000 Odense C Denmark E-mail: coordinator@livergalaxy.eu

The coordinator will be exclusively in charge of the following:

- 1. Chairs all meeting of the Steering Committee (can be delegated to another member of the Steering Committee).
- 2. Prepares the agenda for meetings.
- 3. Monitor that the action in implemented properly.
- 4. Is primary contact person between the GALAXY consortium and the European Commission.
- 5. Request and review any documents or information required by the European Commission and verify their completeness and correctness before passing them on to the European Commission (e.g. certificates of Financial Statements)
- 6. Submit deliverables and reports to the commission.
- 7. Administers the financial contribution from the European Commission to partners.

#### 4.3.2 PROJECT MANAGER

Dr. Linda Sevelsted Møller Department of Gastroenterology and Hepatology University of Southern Denmark Sdr. Boulevard 29 5000 Odense C Denmark E-mail: projectmanager@livergalaxy.eu

The project manager works with all resources to perform project planning. All project and subsidiary management plans will be reviewed and approved by Coordinator.

The project manager is responsible for:

- 1. Supporting the Coordinator to ensure implantation of action, by tracking the progress of deliverables at all times.
- 2. Keeps updated list of all key contact personal.



- 3. Receives reports from WP leaders and writes up quarterly progress reports for the overall project as well as reports to the European Commission to be approved and submitted by the Coordinator.
- 4. Arrange meetings for the Steering Committee, and track minutes of meetings.
- 5. Administers the website.
- 6. Responsible for internal communication forum in GALAXY by providing templates, uniform logo, progress report templates etc.
- 7. Drafts plans for project infrastructure, communication, dissemination, exploitation and risk supported by appointed special managers.

#### 4.4 CONFLICTS

Disputes within the project should be settled as "local" as possible. For practical purposes this will be in the hands of the respective work package leader. Assistance towards conflict resolution can be obtained from the Project Management Office with assistance from the risk manager. Conflict that cannot be solved in this manner should be raised before the Steering Committee. The Steering Committee has the authority to pass a solution by the voting rules outlined in the Consortium Agreement.

#### **4.5 PROJECT CHANGES**

Changes to the project must be carefully considered and the impact of the change must be clear in order to make any type of approval decisions. Changes to the project plan must ultimately be approved by the funding authority. Proposal for changes must be submitted and approved by the Steering Committee.

Any Party may submit a change request for the project to the Steering Committee. All change requests will be logged by the Project Manager and tracked through to completion whether approved or not.

#### **5. WORK BREAKDOWN STRUCTURE**

GALAXY is subcontracted into 8 work packages. The milestone plan includes the schedule baseline for monitoring progress of the project. The Management Office will use various management tools for schedule baselines (Grant charts ect.) to oversee progression of the project as well as deadlines for reporting.

The project manager will also determine the impact of changes or delays to the project progression.

The work packages are divided by the following overall tasks:

- 1. Clinical studies: all necessary samples and clinical data are collected from a running cross-sectional study of patients with alcoholic liver disease together with healthy controls. In addition, two interventional studies are included to validate the therapeutic effect of an antibiotic, Rifaximin, and a synbiotic, Profermin.
- 2. Multi–omics; metatranscriptomics, metagenomics, genomics, transcriptomics and data mining are applied to a selection of samples to gather an exhaustive, comprehensive host/microbiome data warehouse.



- 3. Metabolomics; metabolites play a crucial role during the pathogenesis, therefore metabolites, including bile salts, are analysed and added to the GALAXY data warehouse.
- 4. Systems modelling; systems medicine tools will be developed to analyse the data warehouse and extract key networks during alcoholic liver disease.
- 5. Animal models; key networks will be validated and further analysed in ALF animal models to elucidate causal mechanisms.
- 6. Biomarker development; building upon identified key networks and causal mechanisms, we will identify biomarkers based on host and microbiome -omics characteristics. Biomarkers will be validated in the Profermin study.
- 7. Socio-economic analysis; cost-benefit analysis will be performed to analyse opportunities and identify high potential biomarkers and treatments to enter the clinic.
- 8. Project management; providing all work packages with support in all management related issues.

## 6. PROJECT DELIVERABLES & MILESTONES

Deliverables for the individual work packages are specified in annex 1 of the grant agreement. The work package leader has the overall responsibility of assuring that deliverables are completed on time. Any delays must be reported to the Project Management Office in the quarterly progress reports (se section 9.1), but preferably as soon as possible. It is also required that a clarification as to why delays have accorded is attached, as well as a proposed solution to the delay.

The chart below lists the major milestones for GALAXY. This chart is comprised only of major project milestones such as completion of a project phase. Smaller milestones are not included on this chart. In case of any scheduling delays that may impact a milestone or delivery date, the Project Management Office must be notified immediately so proactive measures may be taken to mitigate slips in dates.



|  | Year 1                                | Year 2                                | Year 3      | Year 4                                | year 5      | year 6      |
|--|---------------------------------------|---------------------------------------|-------------|---------------------------------------|-------------|-------------|
|  | Q1 Q2 Q3 Q4                           | Q1 Q2 Q3 Q4                           | Q1 Q2 Q3 Q4 | Q1 Q2 Q3 Q4                           | 01 02 03 04 | 01 02 03 04 |
| WP1 Clinical studies                         |                                       |                                       |             |                                       |             | ,           |
| 1.1-1.5: Study 1; early ALD patients         |                                       | 1 A                                   | <b>*</b>    |                                       |             |             |
| 1.6-1.10: Study 2; healthy controls          |                                       | x                                     |             |                                       |             |             |
| 1.11-1.15: Study 3; Rifaximin intervention   |                                       |                                       | *           |                                       |             |             |
| 1.16-1.23: Study 4; Profermin intervention   |                                       |                                       |             |                                       | <b>*</b>    |             |
| WP2 Multi-omics of host/microbiome           |                                       |                                       |             |                                       |             |             |
| 2.1-2.5: Samples study 1,2,3                 | 4                                     |                                       |             |                                       |             |             |
| 2.1-2.5: Samples study 1,3                   |                                       |                                       |             |                                       | 100         |             |
| 2.1-2.5: Samples study 4                     |                                       |                                       |             |                                       | *           |             |
| WP3 Biochemical metabolomics                 | -                                     | <u> </u>                              | -<br>-      |                                       |             |             |
| 3.1-3.4: Samples study 1,2,3                 |                                       | 10                                    |             |                                       |             |             |
| 3.1-3.4: Samples study 1,3                   |                                       |                                       |             |                                       | (ACC)       |             |
| 3.1-3.4: Samples study 4                     |                                       |                                       |             |                                       |             |             |
| WP4 Systems modelling                        |                                       |                                       | -           |                                       |             | 2           |
| 4.1: Characterisation of gut community       |                                       |                                       |             |                                       |             |             |
| 4.2: Developing -omics tools for integration |                                       |                                       |             | *                                     |             |             |
| 4.3: Data mining Danish registries           |                                       |                                       |             |                                       |             |             |
| 4.4: Identifying multi-omics markers         |                                       |                                       |             |                                       |             |             |
| 4.5: Identifying key mechanisms in ALF       |                                       |                                       |             |                                       | 5           | 7           |
| 4.6: Prioritising biomarkers and targets     |                                       |                                       |             |                                       |             |             |
| WP5 Animal models                            | b:                                    | i va                                  |             | 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 |             |             |
| 5.1: Set-up animal models                    |                                       |                                       |             |                                       |             |             |
| 5.2: Challenge with rifaximin                | · · · · · · · · · · · · · · · · · · · | 1                                     |             |                                       |             |             |
| 5.3: Confirmation human data                 |                                       |                                       | 5           | ~                                     |             |             |
| 5.4: Interventions targeting key effectors   |                                       |                                       |             | 5                                     | -           |             |
| WP6 Biomarker development                    |                                       |                                       |             | · · · · · · · · · · · · · · · · · · · |             |             |
| 6.1: Optimisation animal and clinical data   |                                       |                                       |             |                                       |             |             |
| 6.2: Cross validation with golden standard   |                                       |                                       |             |                                       |             |             |
| 6.3: Validation with study 4 results         |                                       |                                       |             |                                       | *           |             |
| 6.4: Final product development               |                                       |                                       |             |                                       |             | *           |
| WP7 Socio economic                           | - in-                                 | 4)                                    |             |                                       |             |             |
| 7.1: Cost of interventions                   |                                       |                                       |             |                                       |             |             |
| 7.2: Medical impact                          |                                       |                                       |             |                                       |             |             |
| 7.3: Econimic impact                         |                                       |                                       |             |                                       |             | š—7         |
| WP8 Management, diss./expl.                  |                                       | · · · · · · · · · · · · · · · · · · · |             |                                       |             |             |
| 8.1-8.10: All tasks                          |                                       |                                       |             |                                       |             |             |

e 23. Gant chart of GALAXY. Stars represent milestones as indicated in Table 3.2a.

## 7. COMMUNICATION AND DISSIMINATION PLAN

The purpose of this section is to set the framework for communication for the project by defining and elaborating the communicative requirements both in the daily communication between partners and to external bodies. The goal is to ensure that partners and interest groups receive the information they need to know at the appropriate time, as well as to identify roles and expectations for communication.

The project manager serves as communication manager, with the lead role in overseeing communication in the projects, e.g. by planning meetings, conferences and templates as communicative tolls in the project.

#### 7.1 INTERNAL COMMUNICATION STRATEGY

#### 7.1.1 EMAIL CORRESPONDENCES

Correspondences should be kept professional and as brief as possible. Please initiate emails with GALAXY in the topic field, followed by a short description of the subject of the correspondence. To ease email correspondences regarding management issues, email accounts for the coordinator and project manager has been set up:



Project Coordinator Aleksander Krag: <a href="mailto:coordinator@livergalaxy.eu">coordinator@livergalaxy.eu</a>

Project Manager Linda Sevelsted Møller: projectmanager@livergalaxy.eu

Upon request, similar email addresses can be setup to respective work packages.

An updated contact list for partners, members of the Steering Committee and key associates can be found at the private project forum at the website <u>www.livergalaxy.eu</u>.

It is imperative that changes in contact information are notified to the project manager immediately.

#### 7.1.2 Video Conferences

Several meetings will be planned as videoconferences to avoid unnecessary time and expenses for travel activity. Hence, all partners, and most importantly all WP leaders and members of the Steering Committee should setup an account for the videoconferences and notify the project manager of username. The project manager, will prior to the first videoconference, give notification to attendees on the platform used and instructions to setup.

#### 7.1.3 MEETINGS

This section describes the meeting cycle, responsibilities and persons involved. For public meetings including workshops, symposia and conferences please go to 7.2 on external communication and dissemination.

#### Project team meetings:

As GALAXY involves a number of research groups, the partner and/or WP leader plan meetings within the individual project teams. The frequency of the meetings will vary among partners. Track of meeting minutes is recommended, but is not required.

#### Internal WP meetings:

Collaborations between the individual work packages in GALAXY are a key aspect. The work package leaders are responsible for the arrangement of these meeting when needed. Minutes of meetings should be tracked and send to the project manager as part of the quarterly progress reporting (section 7.1.4).

#### Steering Committee (SC) meetings:

Meetings within the Steering Committee will take place quarterly, alternating between video conferences (section 7.1.2) and physical meetings. The overall purpose of the meetings is to review project status for the previous 3 months and plans for the following year.

The Management Office will outline meeting dates 3 months in advance; the agenda for the SC meeting will be distributed 4 weeks in advance, for comments and suggestions. The finalized agenda will be available 1 week before the meeting.

When needed, additional video – or phone conferences can be scheduled and requested by any



partner. Notification of additional meetings should be given at least 14 days prior to the meeting.

The project manager tracks meeting minutes, and will distributes these to the partners no later than 14 days after the meeting.

#### Advisory board meetings:

Meetings with the advisory board will take place once or twice yearly. The dissemination manager and the project coordinator are responsible for planning meetings with the advisory board, and also to invite the members to selected GALAXY meetings, e.g. workshops and symposia. The project manager tracks meeting minutes, and distributes to partners no later than 14 days following the meeting.

| Meeting<br>Type                  | Description   | Reporting              | Frequency | Participants/<br>Distribution       | Responsible                              |
|----------------------------------|---|------------------------|-----------|-------------------------------------|--|
| Project Team<br>Meeting          | Meeting to review<br>action register and<br>status          | Not required           | Ad hoc    | Project Team                        | Partner                                  |
| Internal WP<br>meetings          | Collaborations<br>between work<br>packages                  | Minutes of<br>meeting  | Ad Hoc    | WP leaders, project<br>team members | WP leader                                |
| Steering<br>Committee<br>Meeting | Review project<br>status                                    | Minutes of<br>meetings | 3 months  | SC members                          | Coordinator/<br>Project manager          |
| Advisory<br>Board<br>Meeting     | Review of designs<br>or work associated<br>with the project | Minutes of<br>Meetings | 6 months  | Project Team                        | Dissemination<br>Manager,<br>Coordinator |

#### 7.1.4 MINUTES OF MEETINGS

Meeting minutes record decisions taken and the actions required by partners. Ultimately the chair of the meeting is responsible to pointing out the referent for taking of the minutes.

A template for minutes will be available at the GALAXY website. If not used, the minutes of meeting should include: date, location, attendees, agenda and action.

The meeting minutes must be send to the project manager, who will create a private project filestore as a permanent record of the meetings.



#### 7.1.5 Website Forum & Private project forum

The GALAXY website <u>www.livergalaxy.eu</u> has been created and will be fully operational by July 1<sup>st</sup> 2016. The website consist of both a public platform as well as a private site for partners. To access the private site, partners and project team members must register on the log in site at the first visit, and will hereafter, upon approval from the project manager, be granted access. The private forum will give project members access to all necessary templates, contact information etc. Project members will here also have opportunities to post messages of interest to all partners. The login site serves the purpose of sharing private, but not strictly confidential information.

#### 7.1.6 TEMPLATES

We encourage all partners to use the GALAXY templates for posters and PowerPoint presentations upon presentations related to the project. This is not a requirement, whereas the use of EU and GALAXY logos are.

Templates for meeting minutes and quarterly progress reports will also available at the project forum at the website before July 1<sup>st</sup> 2016.

#### 7.1.7 FILE SHARING

Operational tools and rules for sharing data among partners will be elaborated in a separate data management plan. Due to the importance of this plan, it serves as a separate deliverable, which will be distributed to all partners and disseminated public on the website within the deliverable due date on July 1<sup>st</sup> 2016.

#### 7.2 EXTERNAL COMMUNICATION AND DISSIMNATION STRATEGY

Upon external commucation from GALAXY all partners are obligated to use the EU emblem and the GALAXY logo. The logos are available for download from the log in site at the GALAXY website.

It must furthermore be stated that the project is supported from the EU by use of the phase "*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No* 668031".

#### 7.2.1 PUBLIC WEBSITE

The GALAXY website <u>www.livergalaxy.eu</u> serves as an important tool for all external communication from the project. It introduces the project to the public and provides information on the individual work packages and links to partners. Dissemination activities will also be announced here, as well as publications and deliverables that must be disseminated on a public level. Relevant links to other GALAXY profiles, e.g. on social medias, can be found at the website.

The website is administered by the Project Manager with technical support from an appointed Webmaster. All partners are encouraged to give input to website, in the form on news, activities and pictures.



#### 7.2.2 Press Stragegy

For the announcement of the Horizon 2020 grant each partner must plan how they wish to do the announcement, e.g. by sending out a press release from their respective institutions.

Press releases regarding the project should be notified to and coordinated with the Project Management Office. The coordinator will also evaluate the press releases, and results of major public or scientific interest will approved by the Steering Committee. The Consortium Agreement states the access right of the results.

The Project Management Office will also take initiative to press releases.

#### 7.2.3 GALAXY FLYER

The GALAXY flyer will be available for download for all interested (public and partners) by July 1<sup>st</sup> 2016. We encourage all partners to use the flyer in dissemination activities to promote the knowledge to the project.

#### 7.2.4 Public Symposia & Conferences

GALAXY will host a number of public symposia during the projects lifespan.

The Project Management Office will take initiative to plan and execute the symposia in collaboration with all partners.

GALAXY will host at least 2 symposia and 1-2 conferences. To maximize impact, GALAXY will collaborate with other H2020 projects to host the conferences.

#### 7.2.5 Educational Workshops And Courses

GALAXY will host 2-3 workshops though the project period. The purpose of the workshop will be to promote further collaborations among partners, especially at the level of young investigators. The workshops will be hosted by difference partners in the project, but planned in collaborations with the Project Management Office. The overall responsibility for initiation and planning of these workshops lies with the dissemination manager and the coordinator. The workshops will be target oriented and serves at an important educational platform within the project.

Furthermore GALAXY will host 1-2 courses in article writing, with young investigators as target audience.

#### 7.2.6 PUBLICATIONS

GALAXY is obligated to disseminate results according to the Grant Agreement. Hence all publications from the project must be publically available. To ensure open access, publications will be uploaded to the webpage.

The GALAXY consortium has agreed on the following principles regarding authorship:

- 1) Duty of work package (WP) leader to look for opportunities for dissemination
- 2) Main papers (analyses, drafting, etc.) under directorship of WP leader
- 3) All authors must meet authorship criteria
- 4) WP leader takes ultimate responsibility for deciding authorship within these principles
- 5) WP leader takes ultimate responsibility for deciding authorship order



- 6) Coordinating center recognized in all papers
- 7) Generally up to one author per country/network on main papers
- 8) Recognition of rest of platform, where appropriate

Decisions made in consultation with coordinator in event of controversy/conflict

#### 7.2.7 VIDEO AND INFOGRAPHICS

GALAXY will set up a YouTube channel in order to upload education videos and tutorials. All partners are strongly encouraged to send in material. This may include tutorials in ultrasonography and elastometric examinations, laboratory procedures and techniques. Selected presentations from key note speakers at the public GALXAXY symposia will also be uploaded, given approval from the presenter.

#### 7.2.8 SOCIAL MEDIA

All partners should contribute to keeping social media profiles updated. News and updates can be notified to the project manager, who will update the profiles.

GALAXY is on Facebook:

https://www.facebook.com/Galaxy-514907385336140/

The Facebook site will be used for public announcement regarding symposia and news from the project.

A LinkedIn profile will be set up within the project's first 6 month as a collaboration platform between both GALAXY partners and external collaborators.

#### 7.2.9 Dissimination of Research Results to Scientific community and Public Health Organisations

This will include:

- Attendance at international conferences.
- Participation at Alcohol awareness week.
- Close communication with patient associations for idea sharing. Collaboration with the European Liver Patient Association (ELPA) has already been established.
- Collaborations with scientific communities for dissemination of the project. GALAXY will in particular be collaborating with the European Association for the Study of the Liver (EASL)
- As part of work package 1 with clinical studies, a patient advisory board will be established. This will consist of 5-6 patients with alcoholic liver fibrosis and 1-2 nurses specialized in alcoholic liver disease, who will advise GALAXY on quality-of-life matters and patient reported outcomes.



## **8. PROJECT REPORTING**

## **8.1 INTERNAL PROGRESS REPORTING**

All partners must submit quarterly internal progress reports. Templates for this has been distributed to all partners, and is available at the website forum.

The reports must be sent to the project manager no later that 14 days after the end of each quarter. Partners, whose work packages are initiated later in the project, do not need to submit progress reports until their work begins. However they should provide a brief reporting in case of attendances in meetings and dissemination activities.

The project manager will, based on the individual reports submitted by the partners, draft up a quarterly project report for the project as a whole.

The quarterly progress reports will include sections on project status, actions and objective for the quarter to come, deviations from the plan, dissemination activities, meeting attended and resources employed.

#### **8.2 REPORTING TO THE EUROPEAN COMMISSION**

Reporting periods for the European Commission are scheduled every 18 months. The Project Management Office will submit the report, as required, within 60 days following the end of these reporting periods. The reports are based on the reports received from the partners.

Reports to the European Commission consist of periodic technical reports and periodic financial reports.

Technical reports covers the work carried out, overview of the progress, a summary for publication by the Commission and answers to the questionnaire, covering issues related to implementation and the economic and social impact.

The Financial reports covers individual financial statements from each partners, and explanation to use of resources and a periodic statement. To track personal resources used, time registrations must be completed. To ease the process, templates for time registration will be available at the private forum at the website.

Templates and instructions for these reports can be found at participant portal:

http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference\_docs.html

Partners must also fill out Certificates on the Financial statements (CFS) and Certificate on the methodology (CoMUC). Templates can be found at:

http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference\_docs.html#h2020-call\_ptef-ef

#### 8.2.1 Reporting Periods

GALAXY reporting periods are scheduled at:

- 1. Period month 1-18 (Jan  $1^{st}$  2016 July  $1^{st}$  2017)
- 2. Period month 19-36 (July  $1^{st}$  Jan  $1^{st}$  2019)
- 3. Period month 37 54 (Jan  $1^{st}$  July  $1^{st}$  2021)



4. Period month 55 - 72 (July 1<sup>st</sup> 2021- Jan 1<sup>st</sup> 2022)

## 9. PROJECT FINANCING

The budget for the each partner can be found in the Grant Agreement. A more detailed table for the distribution of payments from the European Commissions to partners will shortly be available at the private project forum at the GALAXY website.

All partners are responsible for notifying the project manager immediately in case of changes in bank account information.

## **10.** AUTHORIZATION

Approved by the Project Coordinator:

March 18 2016

Aleksander Krag